

DOCKET NO.: OVIT-0283
Application No.: 10/771,077
Office Action Dated: March 29, 2005

REMARKS

Applicants request that claims 1-31, 44-62, and 72 be cancelled without prejudice for filing in a continuing application. The rejections of these claims are considered moot. Claims 41 and 69 has been amended to correct a typographical error. Claims 71 and 73-77 have been amended, support for which may be found throughout the specification, for example in paragraphs 0018, 0036, 0052, and 0060-0061. No new matter has been added.

Pending claim 63 stands rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent No. 6,383,519 to Sapienko et al. ("the Sapienko patent"). Applicants traverse this rejection as there is no showing of a graft material having interconnected macro-, meso-, and microporosity comprising a polymer and beta-tricalcium phosphate. In the Sapienko patent, there are bodies that may be "reinforced with polymers" (Col. 4, ln 31-34), but there is no showing that the body maintains macro-, meso-, and microporosity after being reinforced with polymer. Therefore, each and every element of the claimed invention is not disclosed. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (anticipation is established only if each and every element set forth in a claim is found in a single prior art reference). Applicants respectfully request that this rejection be reconsidered and withdrawn.

Pending claims 32-40, 63, 67-71, and 74-78 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 4,795,467 to Piez et al. ("the Piez patent ") in light of the Bachand document. Pending claims 63-66 and 73 also stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Piez patent in light of the Bachand document, in view of U.S. Patent Nos. 6,458,162 to Koblish et al. ("the Koblish patent"), 5,964,809 to Lin et al. ("the Lin patent") and 5,290,289 to Sanders et al. ("the Sanders patent"). However, the Office Action makes no mention of the Bachand document in the substantive portion of his remarks with respect to these claims. Also, Applicants object to the use of the Bachand document as it has not been shown to be a proper 103(a) reference. As required by 37 CFR 1.104(d) and MPEP § 707.05(e), IV, the date of publication of an electronic document must be given. Applicants' respectfully request that a date of publication be produced or that this rejection be withdrawn.

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Applicant's agree that Piez does not teach bone grafts having macro-, meso-, or microporosity, but do not agree with the Office Action's claim that "it would have been obvious to one of ordinary skill in the art to use a mineral particles with varied mesh sizes in order to achieve macro-, meso-, and microporosity in the bone graft material." (See Office Action, at page 9). The motivation given by the Office Action is that one skilled in the art would obtain such porosity by using "mineral particles with varied mesh sizes." (See Id.) However, this motivation is flawed. Piez teaches a preferred pore size range of 100-2000 μ m. (see col. 3, lines 10-11) while macro-, meso-, and microporosity as defined in the applicants' specification in paragraph 0045 includes pore diameters below about 10 μ m. Piez, therefore, teaches away from the present invention that has macro-, meso-, and microporosity. No motivation has been given to overcome Piez' teachings to obtain the present invention. As such, Applicants respectfully request withdrawal of this rejection.

A review of the art, specifically the Sapieszko patent, shows that one skilled in the art would not achieve macro-, meso-, and microporosity by compressing particles together as taught by the Piez patent. Also, even if one were motivated and properly guided to obtain such porosity in the calcium phosphate of a graft, there has been no showing that once the calcium phosphate has been imbibed with a polymer or collagen, the graft maintains its macro-, meso-, and microporosity as claimed in the present invention. As explained in paragraph 0037 of the present application, "the superior resorption properties of the present invention" may be explained by "the high degree of porosity retained even upon admixing the collagen with the reaction product." In some embodiments this reaction product is calcium phosphate or beta-tricalcium phosphate. Piez teaches that the collagen gel content is "limited to the void space between the HA particles." (See Piez, col.5, lines 63-65). No such, limitation has been shown in the present invention. Therefore, this rejection should be reconsidered and withdrawn.

No proper motivation has been provided for the combination of Piez and Koblish patents. The Office action states that the Koblish patent "[teaches] a similar bone graft material" to the Piez patent. However, this is not the case as it has not been shown that the Koblish patent teaches a graft material having, according to the Examiner, calcium phosphate and collagen as taught by Piez or a bone graft comprising a polymer and beta-tricalcium phosphate as presently claimed. The Koblish patent teaches using a "solid material" that may

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be metal but not a mesh. To cure this defect, the Office Action argues that “it would have been obvious to one of ordinary skill in the art . . . to alternatively use a mesh material in place of a solid material . . .to allow for less restricted flow of biological materials.” (Office Action at page 15). The Applicants traverse this assertion as it is a conclusory statement of generalized advantages and convenient assumptions about the state of the art and are inadequate to support a finding of motivation. *See In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002). The state of the art as depicted in the Koblisch patent states that only solid materials were considered. Materials that were mesh like, or “spongiform,” were considered undesirable and only useful in the formation of RPR product and not for final use. (see the Koblisch patent at column 27, lines 37-43). The Office Action’s statements do not appear to be based on common knowledge in the art as they are not supported by the teachings of the references of record. As such, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Pending claims 70, 71, and 75 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over the Sapienko patent. Applicants have amended claim 71 to include the subject matter of claim 72. Applicants traverse the rejection of claim 75 based on the Sapienko patent. Claim 75 was dependent from claim 72, which described an embodiment comprising a mesh. Claim 72 was also not rejected in light of Sapienko. Applicant’s respectfully request that this rejection be withdrawn.

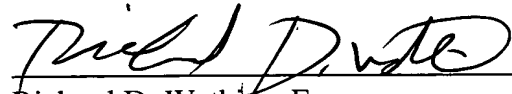
Applicants respectfully request that the provisional rejection of pending claims 32, 63, 67, 71, and 74 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, 11, 20, 23, 28, 37, and 40 of copending Application No. 10/973,781, be respectfully withdrawn. Applicants disagree with the rejection of claims 32, 63, and 67 but submit a terminal disclaimer herewith to advance prosecution of the current application. Claims 71 and 74 have been amended and the rejection of these claims is considered moot.

Pending claims 39-42, 63-67, 70-71, and 73-76 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,736,799. Applicants disagree with this rejection but submit a terminal disclaimer herewith to advance prosecution of the current application.

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Applicants believe that the foregoing constitutes a complete response to the Office Action of record. Applicants respectfully submit that the application is in condition for examination on the merits. Early and favorable consideration, leading to allowance of this application, is requested.

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